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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,446	12/16/2003	Thomas D. Kelly	DI-5928 (112713-457)	8102
29200 7590 04/21/2009 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER DEAK, LESLIE R	
			ART UNIT 3761	PAPER NUMBER
			NOTIFICATION DATE 04/21/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/738,446	Applicant(s) KELLY ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 39-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 February 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 14-16, 19-20, 23, 33-35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 4,702,829 to Polaschegg et al.

In the specification and figures, Collins discloses the apparatus substantially as claimed by applicant. With regard to claims 14, 23, 29, 31, 33-35, 38 Collins discloses a hemodiafiltration apparatus comprising a medical fluid circuit 40, medical fluid supply 50, first pump 62 to supply medical fluid to filtration apparatus 10, second pump 44 operable to pull fluid from the filtering device, and isolating apparatus in the form of

upstream and downstream valves 55, 372 (see FIG 1a, paragraphs 0037-0039). Collins further discloses that the apparatus comprises a substitution fluid filter 92 upstream of the blood filtering device 10, and a flowmeter 68 that is connected to at least outlet of the filter (See FIG 1a). The device further comprises a control unit 110 that uses control schemes to operate the valves and pumps (see paragraph 0042). The controller may operate to close valves 55, 372 in order to place the cartridge in isolation or bypass mode and command pump 62 to deliver a volume of substitute fluid to the patient (see paragraph 0045).

The control scheme disclosed by Collins uses a second, separate replacement fluid supply 300 to deliver a bolus volume to the patient. The Examiner notes, however, that the fluid in reservoir 300 originated in supply 50, which means that the reservoir 300 contains fluid from the first fluid supply. Collins merely uses an intermediate storage location 300 for fluid from supply 50. Accordingly, when in isolation mode, substitution pump 62 delivers a volume of fluid that was originally from fluid supply 50.

Collins fails to disclose that the substitution fluid filter 92 comprises an ultrafilter. However, Polaschegg discloses a medical fluid apparatus that comprises ultrafilters 44 and 78 in the medical fluid circuit upstream of the blood filtration device 12 in order to purify the ultrafiltrate in the event of bolus to a patient (see FIG, columns 5-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use an ultrafilter, as disclosed by Polaschegg, as the substitution fluid filter 92 disclosed by Collins in order to purify the fluid being sent to the patient, as taught by Polaschegg.

In the alternative to the Examiner's interpretation of the fluid sources as disclosed by Collins as presented above, it is the position of the Examiner that the source of the fluid delivered by the bolus is a matter of design choice on the part of the Applicant. Collins discloses that both reservoirs 50 and 300 comprise diasylate fluid, rendering the operation disclosed by Collins functionally equivalent to the operation claimed by Applicant. Applicant has not disclosed that using the same medical fluid supply for both filtration and bolus is for any particular purpose or solves any particular problem. (Arguments of counsel do not comprise objective evidence.) The process disclosed by Collins is the functional equivalent of the process claimed by applicant. Accordingly, it is the position of the Examiner that merely providing a single source of fluid for filtration and bolus as disclosed by Applicant rather than separate sources, as disclosed by Collins, is not a patentable difference from the apparatus disclosed by the cited prior art.

With regard to claim 15, Collins discloses that the volume of fluid issued to the patient is a bolus volume issued to maintain proper patient fluid balance, meeting the limitations of the claims (see paragraph 0045).

With regard to claim 16, Collins discloses that the control scheme is programmed to receive user input before delivery of the bolus (see paragraph 0045).

With regard to claims 19 and 20, Collins discloses that the control scheme relies on input from various pressure and flow sensor devices (such as a blood flow sensor which corresponds to applicant's blood volume sensor) in delivery of the bolus volume (see paragraphs 0011, 0045).

With regard to claim 28, Collins discloses that the apparatus comprises a third pump 42 which is “operable” or “capable” to receive fluid from the tubing areas near isolating valves 55 and 372 and pump it to the rest of the circuit (see FIG 1a).

With regard to claim 36, Polaschegg illustrates that the medical fluid path is configured to deliver medical fluid to the extracorporeal circuit both upstream and downstream of the blood filtering device (see FIG).

4. Claims 17-18 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 4,702,829 to Polaschegg et al, further in view of US 6,830,553 to Burbank.

With regard to claims 17-18 regarding the bolus volume entered by the operator (17) and that the bolus volume is predetermined prior to therapy (18), Collins discloses that the apparatus may provide a specified bolus volume, indicating that it is programmed to receive a bolus amount prior to the therapy. Neither Collins nor Polaschegg disclose that the apparatus is programmed to receive specific instructions from an operator. However, Burbank discloses a blood treatment system that automatically sets operating parameters, but that can be overridden by an operator (see column 31, lines 27-40). It has been held that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (2007). In the instant case, all the elements of the claimed apparatus are known, including a processor that is programmed to accept operator input. Accordingly, it is the position of

the Examiner that the combination of the known elements yields only the predictable result of a medical fluid circuit with a controller that is programmed to receive operator input.

5. Claims 21, 26, 27, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 4,702,829 to Polaschegg et al, further in view of US 5,932,103 to Kenley et al.

In the specification and figures, Collins and Polaschegg disclose the device substantially as claimed by applicant (see rejection above).

With regard to claims 21 and 26, the cited prior art fails to disclose that the bolus delivered to the patient comprises a rinseback volume delivered at the end of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a rinseback fluid that is communicated to the patient after the completion of therapy upon patient input as controlled by the valves, pumps, and optical sensors (see column 48, lines 1-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to program the system disclosed by the cited prior art to deliver a rinseback fluid to the patient after therapy, as disclosed by Kenley, in order to ensure all extracorporeal blood is returned to the patient.

With regard to claims 27 and 32, the cited prior art fails to disclose that the bolus delivered to the patient comprises a prime volume delivered at the beginning of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines

14-20) that also uses dialysis fluid as a priming fluid that is communicated through the circuit before therapy as controlled by the valves, pumps, and air detectors of the circuit (see column 47, line 50 to column 46, line 27).

Response to Arguments

6. Applicant's amendment and arguments filed 18 February 2009 have been entered and fully considered.

7. Applicant's arguments with respect to the rejection(s) of the pending claim(s) under 35 USC § 103(a) to Collins have been fully considered and are persuasive. However, upon further consideration, a new rejection is made over the combination of Collins and Polaschegg, as presented above.

8. Applicant argues that Collins substitution pump is not "operable" to deliver fluid to a blood filtration device, since it operates in a different manner. However, Applicant's claim that the pump is "operable" to perform a particular function requires the ability to so perform. In the instant case, the pump is capable of moving fluid in the direction claimed by Applicant, meeting the limitations of the claims.

9. Applicant requests the rejoinder of Claims 99, and 102-105 to the instantly examined claims. However, claims 99 and 102-105 do not claim all the elements of the apparatus in the presently examined claims (such as a medical fluid supply, ultrafilter with rinse line and flowmeter). As such, the claims are patentably distinct.

Allowable Subject Matter

10. Claims 22, 30, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

12. With regard to claims 22 and 30, the cited prior art teaches a medical fluid circuit with a blood filter, valves, and an ultrafilter, but does not teach that the isolating apparatus comprises a three-way valve, along with the other steps and limitations of the claim.

13. With regard to claim 30, the cited prior art teaches a medical fluid circuit with a blood filter, valves, an ultrafilter, and a controller, but does not disclose or suggest that the controller is programmed to allow periodic flow from a rinse outlet of the ultrafilter to a drain, along with the other steps and limitations of the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
15 April 2009